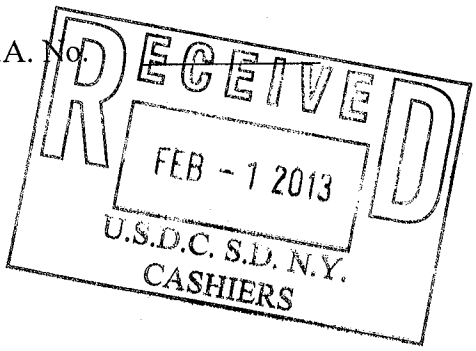
13 CIV 762

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PURDUE PHARMA L.P. and GRÜNENTHAL GMBH, Plaintiffs, v. WATSON LABORATORIES, INC. – FLORIDA, and ANDRX LABS, LLC, Defendants.	C.A. No.



COMPLAINT

Plaintiffs Purdue Pharma L.P. and Grünenthal GmbH for their Complaint herein, aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

THE PARTIES: PLAINTIFFS

2. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431. Purdue Pharma is an exclusive licensee of United States Patent No. 8,309,060 identified in paragraph 12 below. Purdue Pharma is also the holder of New Drug Application ("NDA") No. 022272 for the controlled-release oxycodone pain-relief medication OxyContin®, and is involved in the sales of OxyContin® in the United States.

3. Plaintiff Grünenthal GmbH ("Grünenthal") is a corporation organized and existing under the laws of Germany, having an address at 52078 Aachen, Zieglerstrasse 6, Germany. Grünenthal is the owner of United States Patent No. 8,309,060 identified in paragraph 12 below.

THE PARTIES: DEFENDANTS

4. Upon information and belief, Defendant Watson Laboratories, Inc. – Florida ("Watson") is a corporation organized and existing under the laws of the State of Florida, having a registered address of 4955 Orange Drive, Davie, FL 33314.

5. Upon information and belief, Watson is registered as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions. (Registration Nos. 028681 and 028729). The Registrations have an active status and are valid through October 31, 2013 and December 31, 2013, respectively. Registration No. 028729 identifies Watson's address as 4955 Orange Drive, Davie, FL 33314.

6. Upon information and belief, Defendant Andrx Labs, LLC ("Andrx") is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at the same address as Watson, 4955 Orange Drive, Davie, FL 33314.

7. Upon information and belief, Watson and Andrx are in the same corporate family, and are subsidiaries of the same parent company, Andrx Corp., and the same grandparent company, Watson Pharmaceuticals, Inc. Upon information and belief, Watson and Andrx share certain employees, directors, and/or officers. The same individual, Ms. Janet Vaughn, signed Watson's Paragraph IV Notice Letter as Watson's Director of Regulatory Affairs and signed Andrx's Paragraph IV Notice Letter as Andrx's Director of Regulatory Affairs, which Notice

Letters are described in paragraph 17 below. The same attorney, G. Michael Bryner, Esq., is identified as Watson's in-house counsel in Watson's Paragraph IV Notice Letter and as Andrx's in-house counsel in Andrx's Paragraph IV Notice Letter. Upon information and belief, Watson controls both Watson's and Andrx's filings and submissions with the FDA.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

9. This Court has personal jurisdiction over Watson because, *inter alia*, Watson has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Watson does business in this State and this Judicial District, has engaged in continuous and systematic contact with this State and this Judicial District, and derives substantial revenue from things used or consumed in this State and this Judicial District. Upon information and belief, Watson engages in the manufacture and sale of a range of pharmaceutical products within and directed to the United States, this State, and this Judicial District specifically. Watson did not contest personal jurisdiction in this Judicial District in patent litigations concerning United States Patent Nos. 6,488,963, 7,674,799, 7,674,800, 7,683,072, 7,776,314, and 8,114,383, which suits were based on the same Abbreviated New Drug Application ("ANDA") No. 202352 described in paragraph 13 below that Watson submitted to the FDA based on Plaintiffs' OxyContin® NDA No. 022272. *See Purdue Pharma L.P. et al. v. Watson Laboratories, Inc. – Florida et al.*, C.A. No. 11-civ-2036 (SHS) (S.D.N.Y. Mar. 23, 2011) and *Purdue Pharma L.P. et al. v. Watson Laboratories, Inc. – Florida*, C.A. No. 12-civ-3111 (SHS) (S.D.N.Y. Apr. 19, 2012). Further, this Court has personal jurisdiction over Watson because, upon information and belief, Watson is registered as a

Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions. In addition, upon information and belief, Watson is actively preparing to make the proposed generic copies of OxyContin® that are the subject of ANDA No. 202352, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

10. This Court also has personal jurisdiction over Andrx because, *inter alia*, Andrx has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Andrx, either directly or indirectly through Watson as alleged above, does business in this State and this Judicial District, has engaged in continuous and systematic contact with this State and this Judicial District, and derives substantial revenue from things used or consumed in this State and this Judicial District. Upon information and belief, Andrx, either directly or indirectly through Watson as alleged above, engages in the manufacture and sale of a range of pharmaceutical products within and directed to the United States, this State, and this Judicial District specifically. Andrx did not contest personal jurisdiction in this Judicial District in patent litigation concerning United States Patent Nos. 6,488,963, 7,674,799, 7,674,800, 7,683,072, and 7,776,314, which suits were based on the same ANDA No. 202372 described in paragraph 15 below that Andrx submitted to the FDA based on Plaintiffs' OxyContin® NDA No. 022272. *See Purdue Pharma L.P. et al. v. Watson Laboratories, Inc. – Florida et al.*, C.A. No. 11-civ-2036 (SHS) (S.D.N.Y. Mar. 23, 2011). In addition, upon information and belief, Andrx, either directly or indirectly through Watson and/or in active concert with Watson as alleged above, is actively preparing to make the proposed generic copies of OxyContin® that are the subject of ANDA No. 202372, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

11. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENT IN SUIT

12. Plaintiff Grünenthal GmbH is the lawful owner of all right, title and interest in United States Patent No. 8,309,060 entitled "ABUSE-PROOFED DOSAGE FORM" ("the '060 patent"), including the right to sue and to recover for past infringement thereof. Plaintiff Purdue Pharma is an exclusive licensee of the '060 patent from Grünenthal, with the right to enforce the '060 patent. The '060 patent is listed in the FDA's Orange Book as covering the drug OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, which is the subject of approved NDA No. 022272. A copy of the '060 patent is attached hereto as Exhibit A, which was duly and legally issued on November 13, 2012, naming Johannes Bartholomäus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić as the inventors.

DEFENDANTS' ANDAS

13. Upon information and belief, Watson submitted ANDA No. 202352 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of generic oxycodone hydrochloride extended release tablets ("Watson's proposed generic copies of OxyContin®"), 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, based on the Reference Listed Drug ("RLD") OxyContin®, which is the subject of approved NDA No.022272, before the expiration of the '060 patent.

14. Upon information and belief, Watson's ANDA No. 202352 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '060 patent, listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject

of approved NDA No. 022272, is "invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of [the proposed generic copies of OxyContin®]."

15. Upon information and belief, Andrx submitted ANDA No. 202372 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of generic oxycodone hydrochloride extended release tablets ("Andrx's proposed generic copies of OxyContin®"), 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, based on the RLD OxyContin®, which is the subject of approved NDA No.022272, before the expiration of the '060 patent.

16. Upon information and belief, Andrx's ANDA No. 202372 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '060 patent, listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272, is "invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of [the proposed generic copies of OxyContin®]."

17. In letters dated December 20, 2012 addressed to Plaintiffs and received by Plaintiff Purdue Pharma on December 21, 2012, Watson and Andrx each provided "Notice" with respect to their respective proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, and the '060 patent under 21 U.S.C. § 355(j)(2)(B), and thereby demonstrated an actual and justiciable controversy.

CLAIM FOR RELIEF

18. Watson's and Andrx's submission of their ANDAs was an act of infringement of the '060 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A) with respect to Watson's and Andrx's proposed generic copies of OxyContin®.

19. Upon information and belief, Watson's and Andrx's proposed generic

copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, are covered by one or more claims of the '060 patent.

20. Upon information and belief, Watson's and Andrx's commercial manufacture, use, sale, and/or offer for sale of the proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '060 patent.

21. Upon information and belief, Watson and Andrx have been aware of the existence of the '060 patent, and have no reasonable basis for believing that their proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, will not infringe the '060 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

22. The acts of infringement by Watson and Andrx set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that Watson and Andrx have infringed the '060 patent, and that the commercial sale, offer for sale, use, and/or manufacture of the proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, described in ANDA No. 202352 and ANDA No. 202372 would infringe, induce infringement of, and/or contribute to the infringement of the '060 patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 202352 and ANDA No. 202372 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the date of expiration of the '060 patent plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Watson and Andrx, their officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the '060 patent;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

Dated: February 1, 2013

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